



DEPARTMENT OF HEALTH & HUMAN SERVICES

94722d
Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

April 29, 2004

WARNING LETTER
CHI-8-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Albert A. Zeller, Owner
New Horizons Dairy LLC
4711 Rockwood Rd.
Peoria, IL 61615

Dear Mr. Zeller:

An investigation of your dairy farm operation conducted from January 7 – 8, 2004, found that a dairy cow from your establishment, located at 23318 W. Taggart Rd., Elmwood, IL, was offered for sale for slaughter as human food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You also caused an animal drug to become adulterated because the drug was used in a manner that does not conform to its approved uses or the extralabel use regulations in Title 21, Code of Federal Regulations, Part 530 (21 CFR Part 530). This caused the drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about October 20, 2003, a dairy cow, identified with back tag # 33KT6964 and head tag # 8059, was sold for slaughter as human food to [REDACTED]. United States Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of 0.88 parts per million (ppm) Sulfadimethoxine in the liver tissue, and 0.62 ppm in the muscle tissue. The established tolerance for Sulfadimethoxine in cattle is 0.1 ppm (21 CFR 556.640). The presence of Sulfadimethoxine in the edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act. This violation resulted in a USDA Residue Violation Letter being issued to you on December 3, 2003.

A food is adulterated within the meaning of Section 402(a)(4) of the Act, "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals that are ultimately offered for sale for slaughter under conditions whereby medicated animals bearing potentially harmful drug residues are likely to enter the food supply. Insanitary conditions exist in that you lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those

animals; that drugs are used in a manner not contrary to the directions contained in the labeling; and that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated under Section 402(a)(4) of the Act.

Our investigation found that you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues from edible tissue. You need to implement a system in which to record and maintain permanent drug treatment records that will adequately identify drug-treated animals.

Our investigation also found that you also lack an adequate inventory system for determining the quantities of drugs used to medicate your cows. An accurate drug inventory assures that medications used to treat animals are not being misused and serves as additional assurance that animal treatment records reflect actual dosages administered.

The investigation also determined that you are adulterating the drug Sulfadimethoxine [REDACTED] which was indicated as the cause of your illegal tissue residue, within the meaning of Section 501(a)(5) of the Act when you fail to use the drug in conformance with its approved labeling or the extralabel use regulations at 21 CFR Part 530. Your use of the drug contrary to the directions and without following labeled withdrawal periods causes the drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

The above is not intended as an all-inclusive list of violations. As a producer of animals offered for human consumption, you are responsible for ensuring that your overall operation and the food products you distribute are in compliance with the law.

You should be aware that it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale that was shipped in interstate commerce to be slaughtered is sufficient to make you responsible for violations of the Act.

You should take prompt action to correct the violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct the violations may result in regulatory action without further notice, such as seizure and/or injunction.

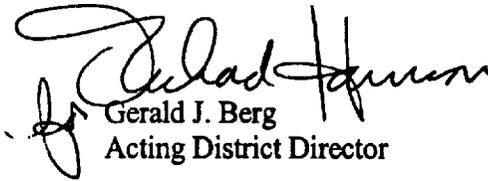
Please advise this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days,

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state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Richard Harrison, Director, Compliance Branch, at the address in the letterhead.

Sincerely,



Gerald J. Berg
Acting District Director

- cc: Mr. William C. Bromlow, Manager
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Elmwood, IL 61529
- cc: Manzoor Chaudry, DVM
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